

REMARKS

Reconsideration of the present Application in view of the above Amendments and the following remarks is respectfully requested. Claims 58, 69, and 71-74 were pending. Applicants hereby cancel claims 69 and 72 without acquiescence to any rejection and without prejudice to prosecution of the cancelled subject matter in a related divisional, continuation, or continuation-in-part application. Claims 58, 73, and 74 have been amended to point out with particularity certain embodiments of Applicants' invention. The specification has been amended solely to remove potential hyperlinks. No new matter has been introduced. Support for the amended claims may be found throughout the specification, for example, at page 12, line 28 through page 13, line 8; page 22, lines 22-29; page 33, lines 10-13; page 39, line 23 through page 40, line 1; and page 42, lines 14-22.

Objections to the Specification

The Action objects to the specification, asserting that the disclosure contains embedded hyperlinks or other forms of browser-executable code. The Action requires that Applicants remove such hyperlinks or browser-executable code, such as at page 55, line 19.

Applicants submit that in view of the Amendments submitted herewith, the specification meets the formality requirements under MPEP § 608.01. Three paragraphs, at page 3, line 11; page 50, line 20; and page 55, line 19, have been amended solely to remove potential hyperlinks to Internet web sites. Applicants therefore submit that the Application meets all formality requirements and respectfully request that this objection be withdrawn.

Rejections Under 35 U.S.C. § 112, Second Paragraph

Claims 58, 69, and 71-74 stand rejected under 35 U.S.C. § 112, second paragraph, for allegedly lacking definiteness. The Action rejects claim 58 and claims dependent thereon, asserting that the relationship among the solid support, array of immunoglobulin molecules and the expression pattern of cell surface antigens on a leukocyte is unclear. The Action also asserts

that the terms “derivative” and “specificity” recited in claim 58 are indefinite and vague. Claims 69 and 72 also stand rejected for allegedly lacking clarity.

Applicants traverse this rejection and respectfully submit that when read in light of the specification, the present claims particularly point out and distinctly claim certain embodiments of Applicants’ invention. With respect to claims 69 and 72, the rejection has been rendered moot in view of the Amendments submitted herewith, which include cancellation of claims 69 and 72 without acquiescence or prejudice.

Amended claim 58 particularly points out that the features of the claimed assay device. The assay device comprises a solid support and an array of immunoglobulin molecules, or antigen-binding derivatives thereof. The immunoglobulins are immobilized to the solid support at 7 to about 1000 discrete regions. Each discrete region of the array comprises an immunoglobulin that is specific for a single cell surface marker antigen (*see, e.g.*, specification at page 33, lines 1-8; page 35, lines 13-14). The array comprises an arrangement of these discrete regions of immobilized immunoglobulin molecules such that specific binding of each immunoglobulin to its respective cell surface marker antigen on a leukocyte provides a pattern of expression that distinguishes leukemias of T-cell, B-cell, or myeloid lineage (*see, e.g.*, page 10, lines 14-20; page 39, line 23 through page 40; line 1; page 42, lines 14-22).

As described in the specification and recited in the present claims, an immunoglobulin molecule, or antigen binding derivative thereof, specifically binds to a single cell surface marker antigen. An immunoglobulin molecule or antigen-binding derivative includes, for example, an antigen binding fragment, fusion antibody, and hybrid antibody, that specifically binds to its respective cognate antigen (*e.g.*, a cell surface marker antigen) (*see, e.g.*, page 33, lines 10-13). The array is an arrangement of immunoglobulin molecules immobilized at 7 to about 1000 discrete regions on the solid support (*see, e.g.*, page 35, lines 9-18). Each discrete region comprises an immunoglobulin that is specific for a single cell surface marker such that the array comprises different immunoglobulin molecules specific for different cell surface marker antigens (*see, e.g.*, page 42, lines 14-22), wherein cell surface marker antigens are selected from the list in Table 4 (*see* page 71). The immobilized immunoglobulins are arranged in the array such that specific binding of each immunoglobulin to its respective cell surface

marker antigen on a leukocyte provides a pattern of expression that distinguishes the leukemias as recited (*see, e.g.*, page 42, lines 14-22; *see also, e.g.*, pages 61-64; Figure 7).

Applicants submit that the present claims particularly point out and distinctly claim the assay device and its features and that the claims, therefore, meet the requirements for clarity and definiteness under 35 U.S.C. § 112, second paragraph. Accordingly, Applicants respectfully request that the rejection of claim 58 and claims dependent thereto be withdrawn.

Applicants respectfully submit that all claims in the application are allowable. Favorable consideration and a Notice of Allowance are earnestly solicited. In the event that the Examiner believes a teleconference will facilitate prosecution of this case, the Examiner is invited to telephone the undersigned at 206-622-4900.

Respectfully submitted,

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